DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 19, 2015

Sybron Dental Specialties
Ms. Kerri Casino
Regulatory Affairs Manager
1717 W. Collins Avenue
Orange, California, 92867

Re: K150559
Trade/Device Name: Life Regular Set and Life Fast Set
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium hydroxide cavity liner
Regulatory Class: II
Product Code: EJK
Dated: March 4, 2015
Received: March 6, 2015

Dear Ms. Kerri Casino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150559

Device Name
Life Fast Set/ Life Regular Set

Indications for Use *(Describe)*
Life Fast Set/ Life Regular Set is a hard-setting Calcium Hydroxide cavity liner and pulp capping agent to be used in conjunction with all permanent restorative techniques.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 6. 510(k) SUMMARY FOR LIFE REGULAR SET/LIFE FAST SET

Life Regular Set/Life Fast Set

1. Submitter Information**:**

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

Contact Person: Kerri Casino
Telephone Number: 714-516-7634
Fax Number: 714-516-7472

Date Prepared: March 4, 2015

2. Device Name:

- Proprietary Name: Life Regular Set and Life Fast Set
- Classification Name: Liner, Cavity, Calcium Hydroxide
- CFR Number: 872.3250
- Device Class: II
- Product Code: EJK

3. Predicate Device:

Proposed Life Regular Set/Life Fast Set is substantially equivalent to the legally marketed device Life 2 (K012717) cleared on October 25, 2001, product code EJK.

4. Description of Device:

Life Regular Set/Life Fast Set are hard setting Calcium Hydroxide cavity liners and pulp capping agents to be used in conjunction with all permanent restorative techniques. Life is a two-part, base/catalyst- paste/paste system. The two-part system is packaged in tubes. The product is available in two viscosities, Fast Set and Regular Set.

5. Statement of Intended Use:

Life Regular Set/Life Fast Set is a hard-setting Calcium Hydroxide cavity liners and pulp capping agents to be used in conjunction with all permanent restorative techniques.

6. Summary of Technological Characteristics:

The **base** formulation of Proposed Life Regular Set and Life Fast Set and the predicate device, Life 2 (K012717), remains unchanged.

The **catalyst** formulation of Proposed Life Regular Set and Life Fast Set and the predicate device, Life 2 (K012717), is very similar, the only difference being the Fumed Silica. The predicate Life 2 (K012717) contains 2-5% Fumed Silica Aerosil R972, CAS# 68611-44-9. The Proposed Life Regular Set and Life Fast Set contain 2-5% Fumed Silica Cab-o-sil TS720, CAS#67762-90-7.

The mixing of the base and catalyst causes the mixture to harden. This is due to a chelation reaction between the calcium hydroxide and the salicylate moieties. The hardening of the thin layer occurs quickly so that the remaining steps of the procedure can proceed. The intention of a cavity base or pulp liner is to protect the pulp from thermal shock.

The fumed silica is added to serve as a filler and rheological modifier. It does not participate in the reaction. The surface treatment of the fumed silica is conducted to make the filler more hydrophobic and to improve the compatibility with the formulation. The difference between a dimethyldichlorosilane treated fumed silica and a polydimethylsiloxane treated fumed silica is insignificant in this formulation. The formulation utilizing the alternative fumed silica has been on the market for a number of years internationally. Based on post market data, the performance characteristics of this material result in equivalent feedback as that of the predicate. The slight variation in fumed silica does not change the performance characteristics of the device.

The primary tube packaging will be changed from a laminate plastic tube to a polyfoil tube, the same tube in which the international version of the product is currently sold and has been on the market for a number of years. The tube filling operation was validated per an internal process validation. Based on the number of years of successful clinical use of polyfoil tubing internationally and successful validation data, the Proposed Life Regular Set/ Life Fast Set tubing change is deemed substantially equivalent to the predicate Life 2 (K012717).

7. Summary of Non-Clinical Performance Data:

Verification and validation activities were performed in accordance with design control requirements as specified in 21 CFR 820.30 and ISO 13485:2012 Medical Devices-Quality Management Systems, and the results demonstrated substantial equivalence to the predicate. Risk analysis for the changes in manufacturing, packaging and formulation was performed utilizing ISO 14971:2012, Application of risk management to medical devices. No new hazards were identified based on post market data from the internationally sold product that has been on the market for a number of years utilizing the proposed manufacturing process, packaging and formulation. The filling process was validated per an internal process validation.

8. Substantial Equivalence:

Life 2 (K012717) is an existing device which was granted market clearance by FDA in 2001. Sybron Dental Specialties seeks only to slightly modify the existing device cleared under K012717. Additionally, the device would be produced at a facility in Scafati, Italy.

The table below depicts the modification associated with Life Regular Set and Life Fast Set.

Table 8.1: Predicate Life 2 (K012717) and Proposed Life Fast Set and Regular Set

Element	Predicate Device- Life 2 (K012717)	Proposed Life Regular Set/Life Fast Set
Trade Name	Life 2	Life Regular Set and Life Fast Set
Target Users	Licensed dental professionals	Licensed dental professionals
Device Description	Life 2 is a hard setting Calcium Hydroxide cavity liners and pulp capping agents to be used in conjunction with all permanent restorative techniques. Life 2 is a two-part, base/catalyst- paste/paste system. The two-part system is packaged in tubes. The product is available in two viscosities, Fast Set and Regular Set.	Life Regular Set/Life Fast Set are hard setting Calcium Hydroxide cavity liners and pulp capping agents to be used in conjunction with all permanent restorative techniques. Life is a two-part, base/catalyst-paste/paste system. The two-part system is packaged in tubes. The product is available in two viscosities, Fast Set and Regular Set.
Common Name	Dental Cavity Liner and Pulp Capping Agent	Dental Cavity Liner and Pulp Capping Agent
Classification Name	Liner, Cavity, Calcium Hydroxide per CFR § 872.3250	Liner, Cavity, Calcium Hydroxide per CFR § 872.3250
Class	II	II
Product Code	EJK	EJK
Base Formula	Formula per K012717	No Change from K012717
Catalyst Formula for Life Fast Set (PN 16530) Only	Contains 2-5% Fumed Silica Aerosil R972, CAS# 68611-44-9	Contains 2-5% Fumed Silica Cab-o-sil TS720, CAS#67762-90-7
Manufacturing Location	Romulus, MI	Scafati, Italy
Packaging	Laminate Tubes	Polyfoil Tubes

Conclusion

The modification of Life Fast Set (PN 16530) to replace the Fumed Silica, the move of manufacturing locations to Scafati, Italy, and the change to the packaging does not affect the intended use of the device nor does it alter the fundamental scientific technology of the device. The nonclinical testing demonstrates that the Proposed Life Regular Set/ Life Fast Set performs as well as the predicate device. Proposed Life Regular Set/Life Fast Set is substantially equivalent to the predicate Life 2 (K012717).